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(54) A COMPLETE HIP-JOINT PROSTHESIS

(71) We, MAHAY & CIE, a French Company, of 10, rue des Pres—20, rue Charles Infroit, 94400 Vitry, Sur Seine, France, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a complete prostheses for the hip-joint.

Many full hip-joint prostheses already exist, which are usually referred to by the name of the surgeon who designed them, for example, the Merle d'Aubigne prosthesis, the Thompson prosthesis, and the Mac Kee prosthesis.

These comprise a cephalic part which is fixed in the femur and a cotyloid part which is fixed in the hip bone.

This fixing is generally carried out with the use of cement, the bone being processed to provide a housing suitable for the shape of the prosthetic part, the said part being fixed in the said housing by cement.

This solution has an important disadvantage due to the fact that the cement reacts on the bone tissue.

It has already been proposed to provide prostheses without cement for the femur piece of the cephalic part, this piece being smooth and inserted just as it is in the bone. But in that case the formation of bone callus must be awaited before the prosthesis is allowed to take any load, and this is very long (up to six or eight months) and involves very difficult re-education work.

The present invention has as its aim to provide a complete hip-joint prosthesis whereby these disadvantages can be obviated, and more particularly a complete prosthesis the fixing of which in the bone does not require the use of any cement and which can be subjected to load almost immediately.

According to the invention there is provided a complete prosthesis for the hip-joint, comprising a cotyloid part adapted to be inserted in the hip bone and a cephalic part adapted to be inserted in the femur, the cephalic part fitting into the cotyloid part, in which the cephalic part comprises a femur piece having a cylindrical externally helically threaded shank portion adapted to be screwed into the medullar canal of the femur and a head part having a base member the underside of which has a bearing surface adapted to abut against a bone surface prepared in corresponding manner, the base member having an arm terminating in a part spherical head for insertion into the cotyloid part and a sleeve depending perpendicularly from and eccentric with respect to the bearing surface, the sleeve fitting in a bore of the same cross-section provided in the femur piece, and means being provided for securing the femoral part to the cephalic head part.

Preferably, the cotyloid part is externally cylindrical and screwthreaded so that it can be inserted in the bone by screwing, and comprises a plane bearing surface perpendicular to the axis of the screwthread, this surface being intended to abut against a bone surface prepared in a suitable way.

Preferably, the cotyloid part is made of metal and is lined internally with a cup made from plastics material held in position by an annular portion inserted in a corresponding groove of the cotyloid part.

Conveniently, the cotyloid part is formed with a screwthreaded wall of smaller height than the total height of the part, the unscrewthreaded end region of the part being dome-shaped. The cotyloid part may have an external bearing shoulder with a diameter larger than that of the screwthreaded wall.

In a preferred embodiment of the invention at least one bore is provided oblique to the longitudinal axis in the cotyloid part for receiving one or more screws which is or are adapted to penetrate into a thick portion of the hip bone to which the part is to be fixed.

An embodiment of the complete hip-joint prosthesis will now be described by way of example only with reference to the accompanying drawings wherein:

Figure 1 shows a lateral exploded view of the cephalic part of a prosthesis according to the invention;

Figure 2 shows in side view the cotyloid part,

Figure 3 and 4 show longitudinal sectional views of the same prosthesis parts respectively;

Figure 5 shows a section taken along the line V—V of Figure 3;

Figure 6 shows in section the prosthesis put in position in the bones of a hip-joint.

Referring now to the drawings in detail the complete prosthesis according to the invention comprises a cephalic part (Figure 1) and a cotyloid part (Figure 2).

The cephalic part (Figures 1, 3 and 5) is formed of a femur piece having a shank 1, which is screwthreaded at its lower portion with a high relief screwthread 2. In the upper portion of the shank 1 there is provided a recess 3 having a cross-section in the form of a regular polygon or the shank is formed with grooves providing detent elements in which a cephalic head part 5 fits by means of its correspondingly shaped sleeve 6. In the example illustrated the cross-section of the recess 3 is octagonal and the cephalic part can take up eight different angular positions relatively to the femur piece. The cephalic head part 5 also comprises a base member having a bearing surface 7 which is perpendicular to the axis of the shank 1. Extending from the base member is an arm terminating in a part spherical head. In an alternative arrangement (see Figure 6) the bearing surface 7 of the cephalic head part 5 may be provided with radial detent elements 22 which engage with corresponding detent elements on the upper face of the shank 1.

A screw 4 connects the shank 1 of the femur piece and cephalic head part 5 to one another so that they are locked together.

The cotyloid part (Figures 2 and 4) is formed of a short screwthreaded cylindrical portion 8 surmounted by a dome 9, the assembly being formed with an internal part-spherical recess 10 lined with a cup 11 of plastics material.

The cup 11 comprises an annular projection 20 corresponding to an annular groove of the part-spherical recess 10, which ensures the retaining of the cup 11 after it has been force-fitted into position.

Lateral bores 12 can be provided for the passage of fixing screws into the hip bone at the regions where the hip bone has portions of extra thickness.

As Figure 6 shows, the cotyloid part can comprise an abutment shoulder 24 which bears on the external face of the pelvis.

The rear face 13 of the screwthreaded portion 8 forms a retaining abutment for the cotyloid part which also comprises longitudinal grooves 14 for positioning it by screwing by means of a tool provided with engaging elements which are inserted in the grooves. An equivalent arrangement would be to provide holes in the shoulder 24 shown in Figure 6.

The fitting of the prosthesis is illustrated in Figure 6 where the hip bone 16 is internally screwthreaded at 15 over a height equal to that of the externally screwthreaded portion 8 of the cotyloid part. At the bottom of the internal screwthread a cup-shaped cavity 23 is bored out in which the dome 9 is located. The cotyloid part of the prosthesis is then put in position by screwing until its rear face 13 comes to abut against the corresponding face of the bone. If necessary, oblique locking screws can be inserted in the lateral bores 12 (see Figure 4) and a shoulder 24 can bear against the surface of the bone 16.

The medullary channel 17 of the femur 18 is drilled and internally screwthreaded with a screwthreading corresponding to that of the shank thread 2 of the cephalic part and the end 19 of the femur is sawn perpendicularly to the internal screwthreading so as to provide a bearing surface for the bearing surface 7 of the cephalic head part 5. The latter is inserted in the shank 1 of the femur piece at the selected angular position and fixed by the screw 4.

It should be noted that the cup 11 of plastics material can be shaped so as to provide a prosthesis of the retention type, i.e. the cup 11 is slightly smaller than the diameter of the ball shaped head of the cephalic head part 5. The ball shaped head must therefore be located in the cup 11 by force so that it is retained therein.

The foregoing description shows that the invention provides a full hip prosthesis the fitting of which does not require any cement and allows load to be accepted immediately, the forces being transmitted by the surfaces at which the parts bear on the bones.

The prosthesis has relatively little harmful effect on the bones, more particularly the hip bone, because of the shallow-depth screwthreading of the cotyloid part surmounted with its dome.

The construction of the cephalic part prevents the rubbing together of metal surfaces whilst utilising the strength of metal. However, it is possible within the framework of the present invention to make the cephalic part from a block of plastics material. The diameters of the cotyloid spherical cup and cephalic head part are preferably identical for prosthetic parts having different dimensions (for example 35 mm), and likewise the dimensional characteristics of the sleeve 6 recess 3 and screw 4. Thus the parts 1, 5 and 4 are interchangeable and match with one another whatever the other dimensions. In this way the surgeon can select for each patient the most suitable size shank of a cephalic part and cotyloid part from a wide range of prosthetic parts which can be pro-

duced having the same number of pieces or moulds.

The prosthesis is particularly strong because of its construction and the arrangement of the bearing surfaces perpendicular to the axis of the shank ensures the best possible transmission of forces.

The prosthesis will preferably be made of chrome-cobalt alloy, but any suitable alloy may be used.

Although in the foregoing description the sleeve 6 and the recess 3 have been given a polygonal (octagonal) cross-section, it would be an equivalent arrangement to make them in the form of grooved cylinders or cylinders with longitudinal splines or with detent elements 22 on the engaging bearing surfaces which are perpendicular to the axis of the shank. Any known means for allowing the shank 1 and the cephalic head part to take up a large number of possible angular positions relatively to one another without rotation being possible after fitting is to be considered as an equivalent.

WHAT WE CLAIM IS:—

1. A complete prosthesis of the hip joint, comprising a cotyloid part adapted to be inserted in the hip bone and a cephalic part adapted to be inserted in the femur, the cephalic part fitting into the cotyloid part, in which the cephalic part comprises a femur piece having a cylindrical externally helically threaded shank portion adapted to be screwed into the medullar canal of the femur and a head part having a base member the underside of which has a bearing surface adapted to abut against a bone surface prepared in corresponding manner, the base member having an arm terminating in a part spherical head for insertion into the cotyloid part and a sleeve depending perpendicularly from and eccentric with respect to the bearing surface, the sleeve fitting in a bore of the same cross-section provided in the femur piece, and means being provided for securing the femoral part to the cephalic head part.

2. A prosthesis according to claim 1, in which the cotyloid part has an externally screwthreaded cylindrical wall, adapted to be inserted in a hip bone by screwing, and a plane bearing surface perpendicular to the axis of the screwthread, adapted to abut against a prepared bone surface.

3. A prosthesis according to claim 2, in which an internal surface of the cotyloid part is lined with plastics material.

4. A prosthesis according to claim 3, in which the cotyloid part is made of metal and the lining is a cup of plastics material held in position by an annular portion inserted in a corresponding groove of the metal cotyloid part.

5. A prosthesis according to any of claims 2 to 4 in which the screwthreaded wall of the cotyloid part has a height less than the total height of the cotyloid part, the unscrewthreaded end region of the part being dome-shaped.

6. A prosthesis according to any of claims 2 to 5 in which the cotyloid part is formed with a bearing shoulder at one end, the diameter of which is greater than that of the screwthreaded wall.

7. A prosthesis according to any of claims 2 to 6 in which at least one bore is provided oblique to the longitudinal axis in the cotyloid part for receiving one or more screws which is or are adapted to penetrate into a thick portion of the hip bone to which the part is to be fixed.

8. A prosthesis according to any of claims 2 to 7 in which the screwthreaded wall of the cotyloid part is formed with longitudinal grooves in which the engaging elements of a screwing tool can be inserted.

9. A prosthesis according to claim 1 wherein the sleeve is tubular and is fitted coaxially in the femur piece.

10. A prosthesis according to claim 1 wherein the securing means is a screw means passing through the sleeve and being screwed into the femur piece.

11. A prosthesis according to claim 10, wherein the cephalic head part includes cooperating means for preventing angular movement of this part relative to the femur piece, the assembly being locked in the selected angular position by the screw means passing through the sleeve and being screwed into the femur piece.

12. A prosthesis according to claim 11, wherein the co-operating means is provided by the sleeve and the recess being of substantially identical polygonal cross-section.

13. A prosthesis according to claim 12, wherein the co-operating means further includes in one of the cephalic parts which cooperate with corresponding detent elements in the other of the parts.

14. A complete prosthesis for the hip, substantially as herein described with reference to the accompanying drawings.

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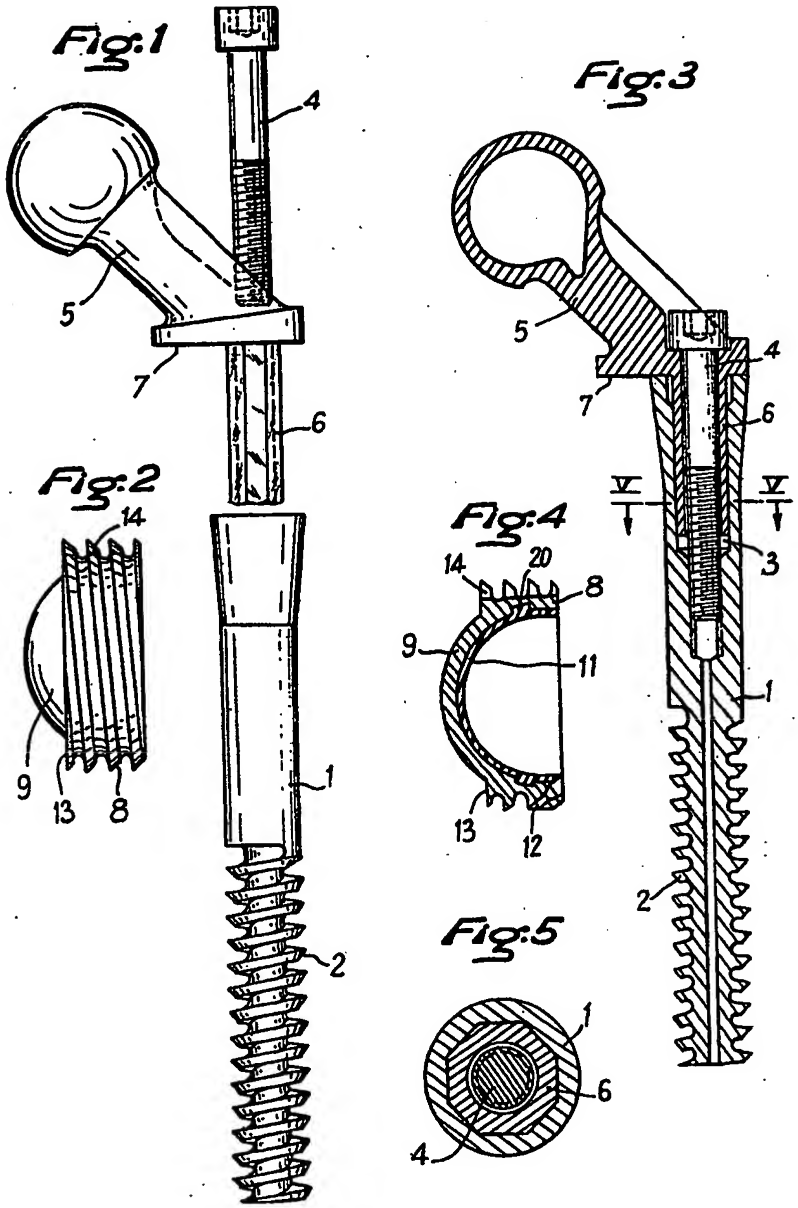
1531487 COMPLETE SPECIFICATION

2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1



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2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 2

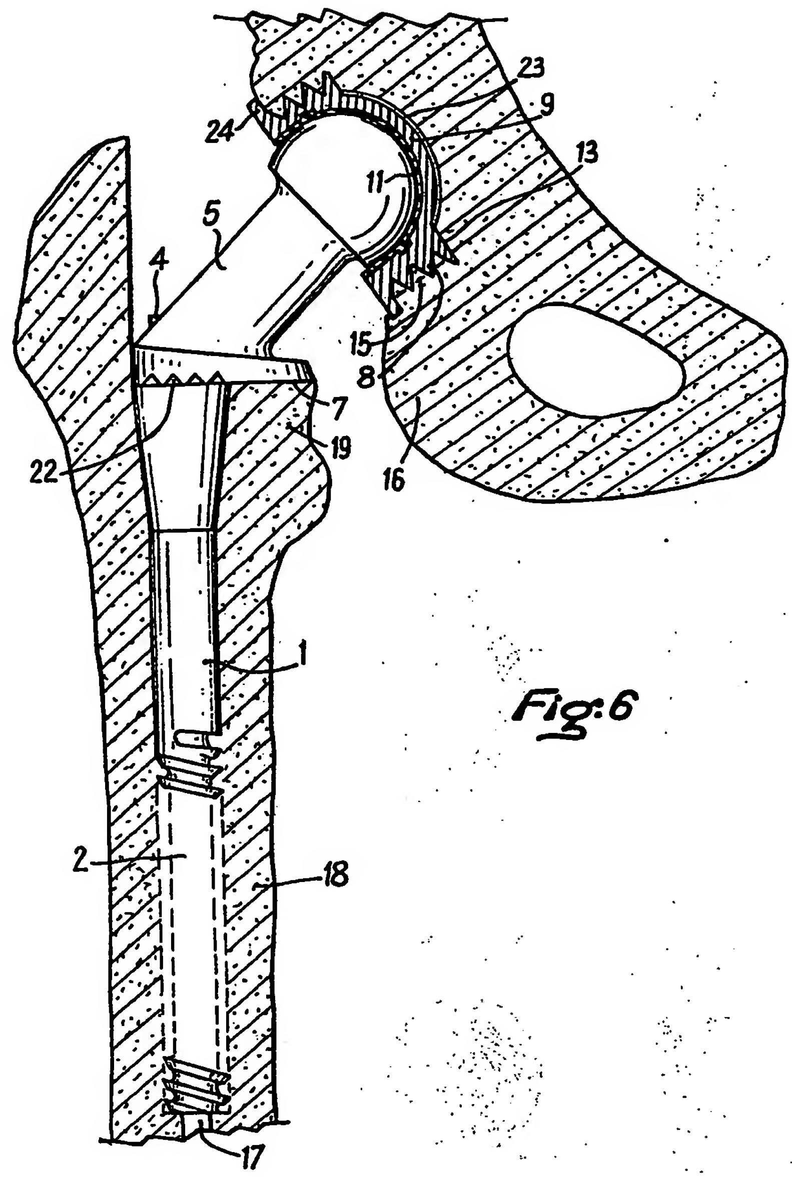

Fig:6

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(p.115, column 1)

57. Area covered by the Request to Register a Practical Use of a New Device

1. Made of ceramic 5, which is formed in similar shape and measurement to the spinal column intervertebral disc 7 and/or vertebral body 100; a ceramic spinal column prosthetic material that resembles a honeycomb, composed of many pillar-like holes 4 with effective openings of diameter 0.2 mm or more to allow for increase, entry and development of this bone structure 7 and/or 100 with respect to that which is inside the top and bottom surfaces 1 and 2 that come in contact with this spinal column bone structure 7 and/or 100.

2. Material that is mentioned in paragraph 1 of the "Request to Register a Practical Use of a New Device," where the above mentioned pillar-like holes 4 are the blind holes 41 that extend and stop at the inside of each of the top and bottom surfaces 1 and 2 of the above mentioned ceramic 5.
3. Part material that is mentioned in paragraph 1 of the "Request to Register a Practical Use of a New Device," where the above mentioned pillar-like holes 4 are the penetrating holes 42 that pass through the above mentioned ceramic 5 in the lengthwise direction.
4. Part material that is mentioned in paragraph 1 of the "Request to Register a Practical Use of a New Device," where the above mentioned ceramic 5 is an alumina linked crystal, alumina ceramic body, or mullite ceramic body.

Detailed Explanation

This idea involves a ceramic spinal column prosthetic material that is used in treatment in plastic surgery, and relates to spinal column prosthetic material that is made to insert in between the spinal column structure for spinal column plastic surgery.

(p.115, column 2)

With the developments in bio-engineering, treatment involving implants of material (screw pins, blades, etc.) into bone structures have become more common in the areas of dentistry and plastic surgery, taking the place of metal artificial prosthetic material; and in these cases, the applicant has provided various inventions that use ceramic, such as alumina ceramic, that, as implant material, adapt well with bone structures and are not harmful in any way. For instance, there are structures like the ceramic bone implant part material that has many holes at the contact surface area that is indicated in (1976)-116809, where it is imbedded into the bone structure to repair the bone structure through the entry of newly created bone structure through the many air passages created on the front surface area that comes in contact with the bone structure.

However, these implant material for the bone have been for hard, solid structures, and in structures that have relatively little load; thus, to use these as they are, structurally and functionally, for complex and for prosthetic material for the spinal column that has high degree of load, has been deemed difficult from the point of view of strength. However, the spinal column supports body weight,

and when lifting or carrying things, there is significant load placed in the lengthwise direction of the spinal column, and at the same time, because there is constant twisting force applied with the movement of the body, there has been a problem, in terms of strength, in using this type of bone implant material that involves three-dimensional space as prosthetic material.

(p.116, column 1)

For this reason, repair procedure for the spinal column has often been to insert into the patient artificial metal prosthetic material that is durable, or to remove the ileum which is of the same soft structure as the spinal column bone structure, and transplant this into the patient. However, when artificial metal prosthetic material is used, there is a problem with it not adapting biologically, and with harmful effects from corrosion within the body. Also, transplants using ileum requires time and labor with surgery, as well as cause the patient much pain and additional burden.

This idea takes into account the existing situation with the current spinal column prosthetic methods, and aims to provide an artificial prosthetic material that is superior in maintenance, has the strength to withstand sufficient load to the spinal column, has no harmful effects on the body, and adapts well to the body.

The following is a detailed explanation of the spinal column prosthetic material that is presented here.

The spinal column prosthetic material (SCPM) presented here adapts well to the body, is composed of ceramic material that has no harmful effects to the body, can be performed by simply inserting it into the appropriate section, and the point is that it is composed of many pillar-like holes in the lengthwise direction, like a honeycomb, with effective openings of diameter 0.2 mm or more to allow for increase, entry and development of this bone structure, with respect to the part that is inside the surface that comes in contact with the ceramic spinal column bone structure.

The effective openings mentioned here refers to that which is necessary for the bone structure that is adjacent to the top and bottom of the SCPM to increase and enter; it is also called the width diameter. Therefore, as long as this width diameter is of a value that allows for increase and entry of adjacent bone structures, the diameter of the pillar holes inside is not a problem.

Also, that the pillar-shaped holes have an effective opening diameter of 0.2 mm or more is a necessary requirement for the effectiveness of the SCPM, where when an adjacent bone structure enters inside the SCPM (the vertebral body that makes up the spinal column is soft compared to the harder ceramic, so the vertebral body bone structure inserts easily into the pillar-shaped spaces of the SCPM, and this fact has already been confirmed in medical experiments), and on the prosthetic area is formed compound structures due to the ceramic and bone structures that have entered and increased. Load on the spinal column in the vertical direction is significant, and there is enough strength to withstand the...

(p.116, column 2)
...force that is put in a twisting direction, and furthermore to easily conduct prosthetics that has maintenance (fixed) strength. Also, with this ceramic, because the prosthetic spinal column in general does not hinder the function it originally has, it goes without saying that it is manufactured in the well known method of "pressure-grind baking" alumina or mullite-type ceramic, with the shape that corresponds to the prosthetic part (for instance, the cervical vertebrae, thoracic vertebrae, lumbar vertebrae, and the intervertebral discs of each). Next, several ideal implementation samples of SCPM will be given, with detailed explanations.

Diagram 1 shows that which is used, among the materials for spinal column prosthetics, for prosthetic intervertebral discs. And also following, in 7 is shown a section of an intervertebral disc that has been removed, and 7 is a healthy intervertebral disc that remains inside the body even after spinal column prosthetics.

Intervertebral disc 7 ... is each of the 100 vertebral bodies that form the spinal column ... and is a fibrous soft structure that communicates to each other. From the point of view of the entire spinal column, it functions as sort of a shock absorber.

This type of incidents where prosthetic intervertebral discs become necessary are caused when, for instance, it must be removed because of problems such as a ruptured disc, and these are times when SCPM becomes especially important.

For instance, as shown in Diagram 2, simply insert the SCPM that is formed into the appropriate shape into the reciprocal spaces of vertebral body 100, 100 that has removed the intervertebral disc 7; and when only one part of vertebral body 100, 100 is removed, the suitable shape of the SCPM should be chosen to suit the part that has been removed.

Thus, when the intervertebral disc 7 undergoes prosthetics, the adjacent bone structures 100, 100 goes into ceramic 5 through holes 41 provided at the top and bottom surfaces. The SCPM 50 forms a compound structure made of ceramic and the bone structures that increase and enter by means of the principles described above, combines strongly with the adjacent tip and bottom vertebral body 100, 100, and becomes a new structure that makes up a vertebral body.

In this case, in place of the intervertebral disc 7 that is a soft structure with high contractibility, a harder ceramic 5 is being used, thus it is no longer possible to fulfill a shock absorber function mentioned above, which existed in a healthy intervertebral disc. This is the same in the transplant case of the ileum (a hard structure) also mentioned above.

(p.117, column 1)

Thus, with respect to the bad effects on the body that existed at times, and poor adaptability to the living body when artificial metal prosthetic materials were used, the SCPM made from ceramic eliminates these problems; and with respect to transplanting the ileum as a means of prosthetics, there is no more need to go through the extraction surgery of the ileum that is troublesome, and a huge burden on the part of the patient. Therefore, it proves to be significantly beneficial in terms of surgery as well as physically.

Furthermore, SCPM can obviously be used for prosthetics that include those cases when the vertebral body itself is missing from the spinal column.

For instance, for prosthetics of missing areas in the spinal column, including the vertebral body, follow Diagram 3 and produce a ceramic in the shape of the desired part, and set screws 61 and 62 onto the top and bottom edges of surface 12 to which the adjacent bone structures 100, 100 are to be connected. If screws 61 and 62 are made so that they are threaded in opposite directions to one another, then screwing and securing onto the adjoining bone structure 100, 100 will be simple and sound, thus favorable.

Diagram 4 shows a prosthetic condition where the SCPM shown in Diagram 3 is put between vertebral body 100, 100.

Other ideal implementation samples of SCPM are shown in Diagrams 5, 6, 7, 8, and 9. Diagram 5 shows top and bottom surfaces 1 and 2 that combine with the bone structure, and instead of the blind hole in Diagram 1, there is ... a slot 42. Diagram 6 shows the top and bottom surfaces of SCPM shown in Diagram 1, ...with multiple rounded protrusions 3, making it easier to insert into the adjacent bone structure, and to have an intervertebral disc that has a stronger connection to the adjacent bone structure. Diagram 7 shows a prosthetic vertebral body with, ... instead of the screws 61 and 62 at the top and bottom edges in Diagram 3, having multiple rounded protrusions 63. Diagram 8 has penetrating holes 41 whose cross-sections are shaped like that of an orange. Diagram 9 shows that with the many passage holes 41. Needless to say, these additional methods...

(p.117, column 2)

...can be applied as deemed necessary. Furthermore, if SCPM is formed to match the shape of the vertebral body part to undergo prosthetics, it is possible to perform prosthetics on various parts of the vertebral body, and especially when doing prosthetics on areas composed of the spinal column including joint areas, set an artificial joint that can freely move forward, preferably within 10°, to the middle range of the ceramic, as necessary.

As mentioned above, the SCPM is adaptable to the body structure more than the common metal prosthetics material, and the structure allows for application of the ceramic as spinal column prosthetic material that is not harmful to the body. It is effective in replacing the bone transplant since it involves simply inserting it into where spinal column prosthetics becomes necessary, and at the same time, it allows for entry, increase and development of the bone structure that is adjacent to the pillar-like holes that lies lengthwise. The ceramic and newly created bone structure form a compound structure that strongly connects to adjacent bone structures, so it maintains strong connection even under added load and lateral deviation force to the spinal column. It is an epoch-making progress in plastic surgery.

A Simple Explanation of the Diagrams

Diagram 1(a) shows one implemented sample (for intervertebral disc) using SCPM, from a diagonal view. Diagram 1(b) shows a diagonal view with one portion cut out. Diagram 2 shows the condition of the SCPM in Diagram 1(a) when used in spinal column prosthetics. Diagram 3 shows another SCPM implementation samples (for the connection part of the intervertebral disc and the vertebral body), from a diagonal view. Diagram 4 shows the condition of the SCPM in Diagram 3 when used in spinal column prosthetics. Diagram 5(a) shows another SCPM implementation sample (for intervertebral disc), from a diagonal view. Diagram 5(b) shows a diagonal view with one portion cut out. Diagrams 6, 8, and 9 are for intervertebral discs, and Diagram 7 shows the implementation sample, diagonal view, of the SCPM, showing each of the connecting parts of the intervertebral discs and the vertebral body.
Explanation of symbols 1 ... top surface, 2 ... bottom surface, 3 ... protrusion, 4 ... pillar-shaped holes, 41 ... penetrating holes, 42 ... blind holes, 5 ... ceramic, 7 ... intervertebral disc, 100 ... vertebral body, 61, 62 ... thread for screw, 63 ... protrusion.